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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,015	02/28/2004	Edwin Burton Hatch		6882

7590 12/06/2006  
Mr. Edwin Burton Hatch  
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EXAMINER

LEFF, STEVEN N

ART UNIT PAPER NUMBER

1761

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/789,015

Applicant(s)

HATCH, EDWIN BURTON

Examiner

Steven Leff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A broad limitation together with a narrow limitation that falls within the limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, and 3-5 recites the broad recitation "transfer(ing) process(es)" and the claim also recites "printing process(es)" which is the narrower statement of the range/limitation.
- With regard to claims 1-5, the claims list different possibilities with respect to how the medicated material can be printed. The claims further list the different types of visual markings and the different types of medicated materials that can be produced. The claims are intended to convey these possibilities as one or the other. For example, one printing process is intended to produce the visual markings, not the use of all of the listed printing processes. However as currently written the claims list all of the possibilities as requirements in order to produce the medicated material. The recitation of a selection from a group of elements in a claim should comply with accepted U.S. Patent practice with regard to the recitation of Markush grouping of claim elements. Phrases using

“comprising” are open sets, and should recite elements in the alternative (i.e. “comprising A, B, C or D”), whereas closed sets (“consisting of”) should recite elements as “selected from the group consisting of A, B, C and D.”

- Regarding claims 1, 3, and 4 the phrase "but not limited to" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- The term "unique" in claims 1, 3, and 4 is a relative term that renders the claim indefinite. The term “unique” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to what would constitute “unique color(s)” and/or “unique pattern(s)”.
- Regarding claims 1, 3, and 4, the phrase "other" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). For example “other marking systems” in the above listed claims.
- With regard to claim 5, the claim is indefinite because either the un-medicated edible product could be heated, or the ink, the medicaments or all of the above. It is unclear as to what is being “heated prior to being printed.”
- Claims 1, 3, and 4 are rendered indefinite due to the phrase “such other data”. It is unclear as to what constitutes “such other data.”
- Claims 1, 3, and 4 are rendered indefinite due to the phrase “as may be necessary”. It is unclear as to what would constitute “necessary to trace manufacture...” For example, the routing number may be necessary, or the state in which the medicated material was produced in may be necessary or they both may not be necessary. It is unclear as to who decided what is necessary and what is necessary.
- Claims 4 and 5 are rejected due to the phrase “produce or create”. There is no patentable difference between producing and creating.
- Claim 3 is rejected due to the phrase “by speeding up”. Speeding up is a relative term, and does not further limit the claim. Another person could view what one person may view as speeding up, differently.

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- Claim 3 is rejected due to the phrase “simplifying”. Simplifying is a relative term, and does not further limit the claim. Reducing the number of steps does not necessarily make a process simpler or easier.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The invention must fall into one of the enumerated statutory classes listed below.

1. A process or method
2. A machine or apparatus
3. A manufacture (article)
4. A composition of matter
5. an improvement of any of the above

For example, claim 1 could read; “A method of printing a medicant with edible ink” or “a method of manufacturing a medicant with edible ink”. As currently written it is unclear in which category the invention would be classified.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by San-EI Chem Ind Ltd. (jp-75013338 B)

San-EI Chem Ind Ltd. (jp-75013338 B) teaches the use of an edible ink powder, for electrostatic printing of medicines or foodstuffs. The ink is produced by mixing together its individual components by melting. The ink may then be applied by screen printing or brush. (abstract)

Therefore since ink is being applied to medicines, and since the purpose of ink, in combination with printing, is to visually provide information, San-EI Chem Ind Ltd. (jp-75013338 B) teaches all of the limitations with regard to printing of medicants with edible ink.

- Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Anhauser et al. (5110599)

Anhauser et al. (5110599) teaches a process for producing an administration and/or dosage form for medicament active substances using a printing process. (abstract)  
The process of Anhauser can be used in the administration form as an orally administrable system, such as a tablet, capsule, etc. (col 2. lines 62 +)

The process of Anhauser permits the production of many components of administration forms, such as adhesive coatings and spots, inscriptions on tablets, active substance-containing areas, etc. (col. 2 line 65+) The ink in the example on page four, discloses the printing medium being produced at a temperature of 21 degrees Celsius.

Therefore with regard to claims 4 and 5 Anhauser et al. (5110599) teach all of the limitations.

### ***Allowable Subject Matter***

There is no allowable subject matter

### ***Conclusion***


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5435840, 5992742, 6796241, 4548825, 5643667, 5534281, 3272118, 3884143, 2931292, 5264224, 5110599, 5017394, 3103165, JP-02024368, 75013338.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Leff whose telephone number is (571) 272-6527. The examiner can normally be reached on Mon-Fri 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571)272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SL

  
**KEITH HENDRICKS**  
**PRIMARY EXAMINER**